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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/692,084	08/08/1996	MOSES RODRIGUEZ	1199-1-001-C	3108

7590 05/20/2004

DAVID A JACKSON
KLAUBER AND JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/692,084	RODRIGUEZ ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-4,9-14 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20-22* is/are allowed.

6)☒ Claim(s) *1-4,9-14 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-1-04 has been entered.

The response and amendment filed 3-1-04 has been entered into the record. Claims 1-4, 9-14 and 19-22 are pending and under examination. Claims 5-8 and 15-18 having been cancelled.

The text of Title 35 of the US Code not reiterated herein can be found in the previous office actions of record.

Rejections Withdrawn

The rejection of claim 22 under 35 USC 112, 2nd paragraph is withdrawn in view of Applicants' amendments.

The double patenting rejection of claim 22 is withdrawn in view of Applicants' arguments.

Rejections Maintained

Double Patenting

Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because the monoclonal antibody of the issued patent anticipates the claims recited herein.

Applicants argue that the double patenting rejection is obviated by the amendments to the claims. This is not persuasive. The monoclonal antibody of the '629 patent is described in this specification as a natural autoantibody that is necessarily synthetic because it is monoclonal. As such, the species of the patent anticipates the instantly claimed genus. It is noted that Applicants argue that the claims are drawn to synthetic autoantibodies, however, the claims as amended recite a monoclonal antibody comprising a synthetic autoantibody. The issued species of the '629 patent still anticipates this claim. Further, a monoclonal autoantibody is necessarily synthetic since it is a product of the hand of man as indicated in the specification and the recitation of "synthetic autoantibody" does not structurally distinguish or functionally distinguish the monoclonal autoantibody of the patent from the claimed antibody. It is noted that synthetic autoantibody is not specifically defined in the specification and as broadly applied includes all monoclonal autoantibodies because they are inherently synthetic due to derivation process of producing the hybridoma to synthesize the monoclonal autoantibody.

The rejection over claim 19 is maintained for reasons made of record.

Claim Rejections - 35 USC § 112

Claims 1-4, 9-14 and 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for stimulating remyelination or treating a demylinating disease in a mammal by administering to a mammal an effective amount of monoclonal antibodies that induce remyelination of the central nervous system, the specific monoclonal antibody SCH79.05 and synthetic monoclonal autoantibodies, it does not reasonably provide enablement for the specific monoclonal autoantibodies A2B5, 01, 04, HNK-1 and synthetic autoantibodies for reasons made of record in all the previous office actions of record.

Applicants argue that clones A2B5, 01, 04 and HNK-1 are public ally available. This is not persuasive, A2B5 and HNK-1 as cited in the ATCC™ catalog is specifically

restricted and not intended for human use. The ATCC™ requires that "Before submitting an order you will be asked to read and accept the terms and conditions of ATCC's Material Transfer Agreement or, in certain cases, an MTA specified by the depositing institution." Further, the ATCC™ products are intended for laboratory use only and not intended for use in humans. As such, these products are in fact restricted in use and practice. Applicants are claiming pharmaceutical use and this product is restricted from that use. As such, it is not freely publically available. (see attached information from the ATCC). As to the recited monoclonal antibody "O1" and "04", this language has been interpreted as the monoclonal antibody with the laboratory designation "O1" or "04". The claims do not support the argued interpretation of a monoclonal antibody that binds the "01" or "O4" oligodendrocyte antigen. As to the 01 and 04 clones allegedly pubically available from R&D Systems, the submitted cover sheet clearly states for research use only and not for use in humans. As such these products are in fact restricted. Applicants are claiming pharmaceutical compositions and methods of use and the products are specifically restricted from that use. Applicants' arguments regarding use of antibodies that recognize the O1 or O4 antigen are not persuasive for all the reasons made of record. The claim is drawn to the monoclonal antibody clone named "01" or "04" and not any monoclonal antibody that binds the 01 or 04 antigen. The claims do not state a monoclonal antibody that binds the O1 or O4 oligodendrocyte antigen. Applicants are specifically cautioned against amending the claims to recite this because the specification lacks apparent written description for such. As to the public availability, the evidence presented indicates that public availability and use is in fact restricted. In order to enable the practice of the invention using the claimed monoclonal antibodies, there must be no restriction. Clearly, these products are restricted. The specification at the time of filing must have enabled the use and the product as claimed. Clearly, the A2B5, 01, 04, HNK-1 monoclonal antibodies as provided for in the ATCC™ catalog and the R&D Systems Catalog are restricted and not available for the claimed use or pharmaceutical composition. This

rejection has been reinstated for the A2B5 monoclonal antibody in view of the evidence of restricted use of the product as set forth in the ATCC™ product catalog. The specification remains non-enabled for synthetic autoantibodies in general as set for the all the previous office actions of record.

Claim 19 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Abo et al (J. Immunol. 127:1024-1029, 1981) or American Type Culture Collection, 1992, page 435 is maintained for reasons made of record.

Applicants argue that the HNK-1 antibody does not factually anticipate the pharmaceutical composition of claim 19. This again is not persuasive, the specification teaches that the HNK-1 antibody is a natural autoantibody (page 13, lines 19-22). Because it is a monoclonal antibody it is inherently synthetic (i.e. the product of manipulation by man). As such, there is no distinguishing features between the claimed monoclonal autoantibody that is synthetic autoantibody and the product of the prior art. The rejection is maintained for reasons made of record. As previously set forth, Applicants have merely discovered a new use of an old composition. This new use does not render the old composition patentably new to the discoverer.

Status of the Claims

Claims 20-22 are allowed. Claims 1-4, 9-14 and 19 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645